

Diversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 09.12.2019

| Product Name | CLEARKLENS CLEANSINALD SC VH9 |
|------------------------|-------------------------------|
| Product Code | 7516429 |
| Batch Number | FMP19344, 49124 |
| Production Date | 10/12/2019 |
| Expiration Date | EXP 10/12/2021 |

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

| Test Test | | Lir | nits | Results | |
|-------------------------|-------------------------------------|---------|----------------------|---------|--|
| | Method | Lower - | - Upper | | |
| Appearance | Visual Clear Slightly Yellow Liquid | | Coor slightly relia- | | |
| pH (neat solution) | DM001 | 12.0 | 13.0 | 12.8 | |
| Specific Gravity (20°C) | DM004 | 1.040 | 1.060 | 1.056 | |
| Cationic content | DM020 | 14.25 | 15.75 | 14.51 | |

| On behalf of Diversey site Quality Manager | Name: | Maralanda Partyusta |
|---|----------|---------------------------|
| | Position | Quality Control Inspector |

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| COA Template Version : 02 Date of issuing : Nov | nber 24 2017 | Date of issuing: November 24 2017 |
|---|--------------|-----------------------------------|
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STERIS: Gamma Certificate Of Processing

Prepared for: FLEXIBLE MEDICAL PACKAGING LTD (8245)

Gamma Process Run ID: 2173-5272A

Product CodeLot NumberQuantityUOMC/SINALD BOTTLES/CAPS/BAGSWO4810411 Case

DV4894

Validation Reference Number: 4894

Processing Run Start Date: 27-Sep-19 11:01 PM
Processing Run End Date: 28-Sep-19 04:49 AM

Specified Dose Range (kGy): 25.0 - 40.0 Calculated Min Dose (kGy): 30.1

Reference Dose Range (kGy): 27.4-36.5 Calculated Max Dose (kGy): 36.9

Gamma Process Run Approval authorized by STERIS

Operating facilities are in compliance with applicable regulations providing services under a certified quality system which meets the requirements of FDA QSR, EN/ISO 13485 current certified version, and is in alignment with EN ISO 11137 current certified version

Processing Location

Synergy Health Sterilisation UK Limited, a STERIS Company Brunel Close Drayton Fields Industrial Estate Daventry Northants NN11 8RB

Phone: + 44(0) 1327 706 111

Items irradiated under WO48104 will be used in finished batch Fmp19344 49124.

Olga Kirchner

Document ID: 29375

Rel Date: 08/13/2018

Last Revised in Rel 2.0.0.0

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Miss Caroline Pascoe

Report of Tests on:

Cleansinald SC

Sample Description:

Sample Code: Fmp19344 49124

Lucideon Sample Number: (196804)-2242

Lucideon Report Number: (196804)-2242/MFEP

Issue Number:

1

Date Logged:

16-Dec-2019

Order Number:

PO34594

Date Reported:

Date(s) of Test(s):

21-Jan-2020 to 04-Feb-2020

07-Feb-2020

Sterility Testing

Membrane Filtration EP

Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report

NOBOOK O7-Ceb-20

Mrs Natalie Boot

Senior Business Support Assistant

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested.